

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 4-18 are pending in the present application. Claims 1-3 have been canceled. Claims 4-7 have been amended to reflect preferred United States patent practice. Claims 8-18 have been added. Claims 8-18 are directed to a method of controlling graft versus host disease (GvHD) in a patient in need of T lymphocyte transplantation. Support for these claims may be found in canceled claims 1-3, which were originally directed to "use" claims. Indeed, at this time, applicants would like to thank the Examiner for taking the initiative of interpreting the "use" claims as method claims.

In the outstanding Official Action, it was indicated that the publication AR was not considered because the citation to the publication in the PTO-1449 Form lacked information concerning the database and database citation information. However, applicants note that these requirements are not found in 37 C.F.R. §1.98 or §609 of the MPEP. Applicants note that Section 700 of the MPEP is directed to the examination of applications by the Patent Office and does not apply here. For the Examiner's convenience, a new PTO Form 1449 citing the publication is attached with this amendment. As a result, applicants respectfully request that the publication be

considered at this time. As the publication has already been submitted, applicants believe that no fee is due.

In the outstanding Official Action, claims 1-3 were rejected under 35 USC §101 for reciting "use" claims.

However, as noted above, claims 1-3 have been canceled. Rather, claims 8-18 have been added, which are directed to method claims. As a result, applicants believe that this rejection has been obviated.

Claims 1-3 were rejected under 35 USC §102(b) as allegedly being anticipated by ANDERSON et al. This rejection is respectfully traversed.

As noted above, claims 1-3 have been canceled. As ANDERSON et al. fails to disclose or suggest a method of controlling graft versus host disease (GvHD) in a patient in need of T lymphocyte transplantation as recited in the claimed invention, applicants believe that ANDERSON et al. fail to anticipate the claimed invention.

Claims 1, 2, and 4-7 were rejected under 35 USC §102(b) as allegedly being anticipated by BUBIEN et al. This rejection is respectfully traversed.

BUBIEN et al. discloses expression vectors encoding human CD20, T cell lines thereby transduced expressing CD20 antigen on their surface, and a method of making a composition of murine antiCD20 antibodies. Apart from the fact that CD20 cDNA-transfected Jurkat T lymphoblasts (Bubien et al., p. 1129, second

column under "Discussion") are different from the human T lymphocytes recited in the claimed invention, the Examiner's assertion that the antibody preparation disclosed by BUBIEN et al. "could be used to remove T lymphocytes ex vivo in patients undergoing GVHD" (Official Action, page 3, point 8 last line) is a speculation, which is not based on the teaching of BUBIEN et al., nor of any other publications cited by the Examiner.

In fact, there is no suggestion in BUBIEN et al. to use surface antigens and antibodies against them to control the activity of donor T-lymphocytes infused into a patient. Rather, the aim of the study by BUBIEN et al. is to investigate the effects of CD20 in terms of regulation of transmembrane  $Ca^{++}$  conductance in CD20-transfected lymphoblastoid cell lines (see abstract). Likewise, antiCD20 antibodies are used by BUBIEN et al. to investigate the changes in cytosolic calcium-ion activity, but nothing is suggested as to the possibility that CD20 may be used as a target for antibodies able to suppress circulating lymphocytes. Thus, the claimed invention is neither disclosed nor suggested by BUBIEN et al.

Thus, in view of the above, applicants believe that BUBIEN et al. fail to anticipate the claimed invention.

Claims 1-7 were rejected under 35 USC §102(a) as allegedly being anticipated by INTRONA et al. Applicants believe that the INTRONA et al. publication fails to qualify as prior art.

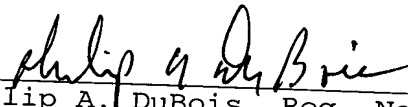
Indeed, at this time, the Examiner's attention is respectfully directed to the verified English translation of the MI99A001299 application, filed on June 11, 1998. As INTRONA et al. was published after this date, applicants believe that INTRONA et al. fail to qualify as prior art.

Thus, in view of the above, applicants believe that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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PD/mjr

**APPENDIX:**

The Appendix includes the following item(s):

- a verified English translation of Application  
No. MI99A001299, filed on June 11, 1998.
- PTO Form 1449